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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,804	06/28/2000	Amy S. Lee	06666-040001	5664

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/606,804	LEE, AMY S.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4. ☒ Newly proposed or amended claim(s) *30* would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *None*.

   Claim(s) objected to: *30*.

   Claim(s) rejected: *1-9,15,16,31-35,37-43,45,46 and 63*.

   Claim(s) withdrawn from consideration: *10-14,17-21,44 and 47-62*.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *See Continuation Sheet*

Continuation of 3. Applicant's reply has overcome the following rejection(s): 112 second paragraph rejection for claims 37-43,45, and 46. 112 first paragraph for claims 38-42, 45 and 46.

Continuation of 5. does NOT place the application in condition for allowance because: See attachment.

Continuation of 10. Other: Claim 42 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 42 depends on claim 38 which is limited to local administration. However, claim 42 recites in vivo administration which is broader than local administration. Claim 43 is objected to because it depends from claim 42.

Claim 30 is free of the prior art of record.

Claim 30 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In the response filed on 3/11/04, Applicant did not address the claim objection for claim 63 in the previous office action mailed on 12/24/03.

Attachment: for continuation of 5:

The 112 first paragraph rejection for claims 37 and 42 remains for the reasons of record. Applicant's arguments filed 3/11/04 have been fully considered but they are not found persuasive. Claims 37 and 42 still embrace using any route of administration in the claimed method and the applicants have conceded that claims 38 and 43 were not enabled for using any route of administration in the claimed methdos by amending claims 38 and 43 to recite local and direct administration. The art of record teaches that using any route of delivery is considered unpredictable. See Verma, supra and Vile, supra. The specificiation only provides sufficient guidance and/or factual evidence for using direct administration. The specification does not teach one skilled in the art how to practice the claimed method using any other route of administration. In view of the In Re Wands Factors, the as-filed specification is only enabled for using a direct route of administration and not for using any other route of administration.

Furthermore, the rejection of claims 1-9, 15, 16, 31-35, 37-43, 45, 46, and 63 under 103(a) over Gazit taken with Walther in further view of Mullen remain for the reasons of record.

Applicant's arguments filed on 3/11/04 have been fully considered but they are not persuasive. NOTE: in the previous argument by applicant for overcoming the 103 rejection, the argument was based on a Declaration under 1.132. The rejection remained because the Gazit article has a 102(b) date and a Declaration under 1.132 cannot be used to overcome the rejection. See MPEP 2133. Now, applicant is arguing that the prior art is not enabled for the reason of record set forth in the 112 first paragraph enablement rejection.

Applicant argues that the patent office has set forth a double standard because the patent alleges that gene therapy and gene delivery are highly unpredictable arts and thus applicants should not be entitled to claim a generic delivery method or gene therapy absent data in specific models under specific conditions. The patent office then alleges that it would be a simple matter to arrive at applicants' gene therapy or gene delivery methods and compositions by merely combining the teaching in the arts. See pages 18-20.

The patent office had not set forth a double standard as asserted by applicants. The 103(a) rejection is based on using direct administration, which corresponds to the scope of enablement rejection under 112 first paragraph.

Furthermore, Applicant argues that in view of the teachings of the references and the position of the patent office, applicant submits that one of ordinary skill in the art would not have any reasonable expectation of success of combining the alleged vector technology of Gazit with the pro-drug gene therapy require a reasonable expectation of success. Applicants submit that the combination of references cited by the examiner is "no more than a plan or invitation for experimentation in view of the art of record exemplifying the unpredictability of gene therapy". See pages 18-20.

Applicant's argument is not found persuasive because the statements by the examiner cited by applicant are directed to why the claimed invention was not enabled for the full breadth of the claimed methods. As stated above, the prior art rejection is based on the scope of enablement under 112 first paragraph. Furthermore, Gazit teaches making and using the claimed vector. The only limitation that Gazit does not teach is using a heterologous sequence

encoding an enzyme that converts a non-therapeutically effective compound to a therapeutically effective compound in vivo in the claimed product and using the claimed product in a method of pro-drug cancer gene therapy. Thus, those limitations are taught by Walther and Mullen. Mullen teaches using in vivo cancer therapy using intracerebral administration (page 205). Furthermore, Applicants assertion is not supported by any evidence. See MPEP § 716.01(c).

Furthermore, with respect to applicant's argument against using the claimed product, the argument is moot because the use of a product has no patentable weight under a prior art rejection. MPEP recites 2112.01 recites: Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established.In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). This is the case here. Applicant has provided no evidence that the claimed product is not identical or substantially identical to the product rejected under 103(a). See In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983) .

Scott D. Priebe

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PRIMARY EXAMINER